



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,718	07/28/2006	Jun Liu	9896-000053/NP	4920
27572 7590 12/23/2008 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 12/23/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,718	<b>Applicant(s)</b> LIU ET AL.	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-21 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3-8, 10, 12, 17-21, 23, 24, 30 is/are allowed.
- 6) ☒ Claim(s) 2, 14-16 and 25-29 is/are rejected.
- 7) ☒ Claim(s) 11 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicants' Response to Notice of Non-Compliant Amendment, received 18 September 2008, is acknowledged. Claims 1-6, 7, 12, 14-16, 18, 19, 21 and 23-29 have been amended. Claim 9 has been canceled. New claim 30 has been added.
2. Claims 1-8, 10-21 and 23-30 are pending and under consideration.

### **Rejections/Objection Withdrawn or Moot**

3. The objection to claim 9 is moot in light of the cancellation of the claim.
4. The objection to claim 25 because in line 2, "Mycobacterium" should be in italics, is withdrawn in light of the amendment of the claim.
5. The objection to claim 28 because line 1, "Mycobacterium bovis" should be in italics; line 2, "Mycobacterium" should be in italics, is withdrawn in light of the amendment of the claim.
6. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite for the source of the "nucleic acid capable of expression", is moot in light of the cancellation of the claim.
7. The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being indefinite for MYCOBACTERIUNA, is withdrawn in light of the amendment of the claim.
8. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite for the source of the "nucleic acid capable of expression", is moot in light of the cancellation of the claim.
9. The rejection of claims 1-8 and 10-20 under 35 U.S.C. 112, second paragraph, as being indefinite for the source of the "nucleic acid capable of expression", is withdrawn in light of the amendment of the claims.

Art Unit: 1645

10. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for which nucleic acids are being claimed, is withdrawn in light of the claim amendment.
11. The rejection of claims 21, 23 and 24 under 35 U.S.C. 112, second paragraph, as being indefinite for underlining of "of serine", is withdrawn in light of the claim amendments.
12. The rejection of claims 25-27 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of the claim amendments.
13. The rejection of claims 28 and 29 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of the amendment of the claims.
14. The rejection of claims 21 and 23-29 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of the amendment of the claims.
15. The rejection of claims 21 and 23-29 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of the amendment of the claims.
16. The rejection of claims 8 and 10-12 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn.

#### **Rejections Maintained**

17. The objection to claim 13 because in line 2, "Mycobacterium tuberculosis" should be in italics, is maintained.

#### **New Rejection/Objection Necessitated by Amendment**

##### **Claim Objections**

18. Claim 11 is objected to because of the following informalities: line 2, there should be a space between 8 and further in "8further". Appropriate correction is required.

#### **Claim Rejections - 35 USC § 112**

19. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1645

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 2 now recites the live strain of claim 1 wherein the at least one protein or polypeptide selected from the group consisting of ..... It is unclear what is to be done with the polypeptide selected from the group.

21. Claim 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to inhibiting the growth of BCG comprising obtaining a sample comprising BCG and culturing the sample in "a selective medium". It is unclear what the medium is selective for.

22. Claim 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of culturing BCG comprising obtaining a sample of BCG and culturing the sample in "a differential medium". It is unclear what the medium is differential for.

23. Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from an objected to claim 13.

Art Unit: 1645

### **Conclusion**

24. Claims 2, 11, 13-16 and 25-29 are rejected or objected to.

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

Art Unit: 1645

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

December 23, 2008